

## **The Office of Research and Development Quality System Assessment Entrance Briefing**

**November 26, 2013**

Purpose of the entrance briefing is to provide senior management an overview of the scope and approach to the Quality System Assessment (QSA) and discuss the on-site activities. It also provides the opportunity to obtain senior management's perspective on the organization's quality system and identify any concerns or expectations about the QSA.

### **Quality System Assessment Oversight:**

- Renee P. Wynn Acting EPA's Chief Information Officer and Acting OEI/AA, Vaughn Noga Acting Deputy AA and Acting Deputy Chief Information Officer have Agency-wide responsibilities for EPA's Quality Policy for environmental data operations (CIO 2105)
- Monica Jones, Director of the OEI Quality Staff has delegated oversight responsibilities for assessing implementation of the policy; we assess environmental programs for conformance and effectiveness every 3 - 5 years. *ORD was last assessed in 2009*
- The ORD-wide Quality Management Plan (QMP), *approved on February 22, 2012* describes the organization's implemented quality system and provides the framework for the scope of this assessment. This is the first assessment of the implementation of the ORD-wide QMP. The QSA will focus on effectiveness of this comprehensive plan for the decentralized, diverse ORD Laboratory/Centers/Office (L/C/O) quality systems. Individual L/C/O QMPs are being aligned with the ORD-wide QMP and will be included as appendices upon the next revision of the overarching QMP
- The QSA assessment team consists of EPA quality assurance experts who are familiar with ORD and often work collaboratively with your QA staff: Vincia Holloman (Lead) and Kevin Kirby of the Quality Staff; Jeff Worthington, Director of Quality Assurance, OEI; Louis Blume, QA Manager GLNPO
- The QSA Assessment Plan was transmitted by the OEI Immediate Office on October, 29 2013. It defines the approach and identifies projects for review and managers and QA staff for interviews

### **The QSA Scope and Approach:**

- The QSA *is unlike an IG audit* which is very narrow in scope and looks for specific weaknesses and deficiencies. In contrast, the QSA objectively evaluates performance of quality programs in compliance with established policies, procedures and practices
- The QSA Team Lead have been collaborating with Lora Johnson, the ORD Director of

Quality Assurance and Lab/Center/Office QA Managers to plan and conduct a QSA that evaluates the new approach to QA for collaborative research under the ORD Research Plans:

- ORD's QA organizational and management structure is moving toward a "one-ORD Approach" to QA with the overarching QMP as the foundation
- Senior management involvement with QA decisions during research planning and resource allocation for collaborative work – *promotes ORD's value for sound science and transparency in decision-making*
- Processes in place for planning QA for matrix managed research projects - *OSIM Deputy Director and SIO, working with the ORD QA community*
- Performance of QA Staff roles and responsibilities – *DQAs, QAMs, PQAMs, Research Cores, Records Manager, Scientific Data Manager, others*
- Management involvement in determining QA requirements for programs and research categories - *SIO, L/C/O Directors*
- QA knowledge management and documentation – *succession planning*
- Processes for cross – ORD communication, outreach and collaboration on QA requirements for the six national research programs – *Branch Chiefs, Project Leads, Task Leads*
- Procedures for resolution of QA conflict
- Implementation of corrective actions and best practices for improvement
- Oversight and documentation of quality-related work:
  - Policy and Procedure Manual, Chapter 13.3 – *QA planning*
  - Policy and Procedure Manual, chapter 14.3 – *ORD clearance processes, IQG*
  - Application of the graded approach in determining QA requirements at the project level – *getting the right data for the right decision*
  - Consistency in use and approval of required QA documents - *QAPP, QARF, SOPs, notebooks*
  - QA compliance for extramural work – *planning, documentation and oversight*
  - Processes for assuring quality of existing data internal/external to EPA – *Use of the Agency's guidance on Assessment Factors*
  - Availability, utility of information management databases and systems
- Continuous internal program evaluation efforts:
  - Conduct of internal assessments – *MSRs, TSAs*
  - QA training, education, development of QA tools (*eLab notebooks*)
  - Reporting of accomplishments & sharing of best practices - *ORD@work; QA Websites, Annual QA workshops/conferences, etc*
  - Opportunities for QA recognition and award
- Planning, conducting and completing the QSA
  - Three site visits are planned for DC (Dec 3, 4); Ohio (December 9, 10, 11); and RTP (January 7, 8, 9)
  - Interviews with identified managers and staff
  - Review of selected projects (biofuels, ISAs, STAR, STREAM)

- Review of QA documentation for grants and contracts (STAR grants, OARS)
- Review of QA planning systems (RMS, HERO, STICS, ORD Work)
- Review of QA tracking systems (QLOG, QATS, QAIMS)
- QSA Report and Follow-up
  - A summary report to be issued by February 2014
  - Findings require a corrective action plan

### **Conclusion/Observations**

- ORD's scientific research supports EPA's decisions and regulation
- *The Draft FY 2014-2018 EPA Strategic Plan states* "We will continue to affirm the core values of science, transparency and the rule of law in addressing our environmental challenges. Our work will be guided by the best possible data and research and a commitment to transparency and the accountability that comes with it"
- Applied Research is incorporated into four of the five strategic goals for FY 2014 - 2018 and the cross-cutting strategies
- QA is the practiced "scientific method – Plan-Do-check-Act" that make the research results credible, defensible and useful
- The QSA helps us determine the soundness of the data and information used by ORD in informing the Administrator's priorities

